PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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330 University Avenue
TORONTO, Ontario
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* 31 August 2007 (31-08-2007)

Applicant's or agent's file reference
9577-61 KAM

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA2007/000862	14 May 2007 (14-05-2007)	12 May 2006 (12-05-2006)

International Patent Classification (IPC) or both national classification and IPC
IPC: ***A61K 9/06*** (2006.01), ***A61K 31/485*** (2006.01), ***A61K 47/02*** (2006.01), ***A61K 47/30*** (2006.01), ***A61K 47/44*** (2006.01), ***A61K 9/52*** (2006.01), ***A61P 25/30*** (2006.01)

Applicant
ODIDI, ISA ET AL

1. This opinion contains indications relating to the following items :

[X]	Box No. I	Basis of the opinion
[ ]	Box No. II	Priority
[X]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[X]	Box No. VI	Certain documents cited
[X]	Box No. VII	Certain defects in the international application
[X]	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**
If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/CA	Date of completion of this opinion	Authorized officer
Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	03 August 2007 (03-08-2007)	Charles Greenough 819-994-0243

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   [X] the international application in the language in which it was filed

   [ ] a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. [ ] This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of :

   a. type of material

      [ ] a sequence listing

      [ ] table(s) related to the sequence listing

   b. format of material

      [ ] on paper

      [ ] in electronic form

   c. time of filing/furnishing

      [ ] contained in the international application as filed.

      [ ] filed together with the international application in electronic form

      [ ] furnished subsequently to this Authority for the purposes of search.

4. [ ] In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments :

Box No. III **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of :

[ ] the entire international application

[X] claim Nos. 67-69

because:

[X] the said international application, or the said claim Nos. 67-69 relate to the following subject matter which does not require an international search *(specify)* :

Claims 67-69 are directed to a method for treatment of the human or animal body by surgery or therapy, are not required to be searched nor is a written opinion required by this Authority. Regardless, this Authority has established a written opinion based on the alleged effect or purpose/use of the product defined in claims 67-69.

[ ] the description, claims or drawings *(indicate particular elements below)* or said claim Nos. are so unclear that no meaningful opinion could be formed *(specify)* :

[ ] the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify):*

[ ] no international search report has been established for said claims Nos.

[ ] a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

[ ] furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

[ ] furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

[ ] pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

[ ] a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

[ ] the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

[ ] See Supplemental Box for further details.

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	6, 8, 11-14, 20, 26, 40-62, 65, 75, 77	YES
	Claims	1-5, 7, 9, 10, 15-19, 21-25, 27-39, 63, 64, 66-74, 76	NO
Inventive step (IS)	Claims	6, 8, 11-14, 20, 26, 40-62, 65, 75, 77	YES
	Claims	1-5, 7, 9, 10, 15-19, 21-25, 27-39, 63, 64, 66-74, 76	NO
Industrial applicability (IA)	Claims	1-66, 70-77	YES
	Claims	NONE	NO

2. Citations and explanations :

D1: US 6 607 751 (Odidi et al.)
D2: US 6 627 635 (Palermo et al.)
D3: US 2006/0039864 (Bartholomaus et al.)
D4: US 4 946 853 (Bannon et al.)

Claims 1-4, 9, 15-19, 21, 23-25, 27-37, 70-74 are not novel and do not comply with Article 33(2) of the PCT. Document D1 discloses a controlled release pharmaceutical device comprising a controlled release agent and a pharmaceutical active such as morphine. The device may also comprise glyceryl stearate and a lubricant such as magnesium stearate or talc. Also, although D1 does not explicitly state the subject matter of claims 24 and 27-37, it is assumed the composition of D1 will react in the same way as it is made up of the same components as claimed in claims 1-4. Given the above objection, claims 1-4, 9, 15-19, 21, 23-25, 27-37, 70-74 are also considered to lack an inventive step in light of the described prior art and thus fails to comply with Article 33(3) of the PCT.

Claims 1, 2, 15-17, 21, 23-25, 27-37, 64, 70, 71, 74 are not novel and do not comply with Article 33(2) of the PCT. Document D2 discloses a sustained release oral dosage form comprising an orally active opioid agonist and a sustained release carrier which may be incorporated in a matrix formulation. The dosage form may also comprise gelling agents and waxes. Also, although D2 does not explicitly state the subject matter of claims 24 and 27-37, it is assumed the composition of D2 will react in the same way as it is made up of the same components as claimed in claims 1 and 2. Given the above objection, claims 1, 2, 15-17, 21, 23-25, 27-37, 64, 70, 71, 74 are also considered to lack an inventive step in light of the described prior art and thus fails to comply with Article 33(3) of the PCT.

Claims 1, 2, 5, 15-17, 21-25, 27-37, 39, 63, 64, 66, 70, 71, 74 are not novel and do not comply with Article 33(2) of the PCT. Document D3 discloses an oral dosage form with controlled release of an addictive substance. The dosage form may also comprise a wax, delayed release matrix auxiliary substances, at least one substance which irritates the nasal passages and a delayed release coating. This dosage form may be packaged in capsules. Also, although D3 does not explicitly state the subject matter of claims 24 and 27-37, it is assumed the composition of D3 will react in the same way as it is made up of the same components as claimed in claims 1 and 2. Given the above objection, claims 1, 2, 5, 15-17, 21-25, 27-37, 39, 63, 64, 66, 70, 71, 74 are also considered to lack an inventive step in light of the described prior art and thus fails to comply with Article 33(3) of the PCT.

Claims 1-5, 7, 9, 10, 15-19, 21, 23, 24, 27-38, 64, 66-74, 76 are not novel and do not comply with Article 33(2) of the PCT. Document D4 discloses a preparation comprising an addictive substance (nicotine) uniformly distributed in a semi-solid medium, said medium comprising a gel-forming agent such as bentonite or hectorite and a solvent such as stearyl alcohol. This preparation may be in the form of a paste. Also, although D4 does not explicitly state the subject matter of claims 24 and 27-37, it is assumed the composition of D4 will react in the same way as it is made up of the same components as claimed in claims 1-5. Given the above objection, claims 1-5, 7, 9, 10, 15-19, 21, 23, 24, 27-38, 64, 66-74, 76 are also considered to lack an inventive step in light of the described prior art and thus fails to comply with Article 33(3) of the PCT.

Claims 6, 8, 11-14, 20, 26, 40-62, 65, 75, 77 are novel and are considered to involve an inventive step and comply with Articles 33(2) and 33(3) of the PCT.

The subject matter of claims 1-66, 70-77 is considered to be industrially applicable and thus complies with the requirements of Article 33(4) of the PCT.

Box No. VI **Certain documents cited**

1. Certain published documents (Rules 43*bis*.1 and 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
US 2007/0104778	10-05-2007	14-05-2007	12-05-2006

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted :

The description does not comply with Article 5 of the PCT. All documents referred to in the description of an application must be available to the public. Reference to the document on page 1, line 2 must be deleted or replaced by its corresponding patent number or publication number.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made :

Claims 24, 27-37, 46-56 do not comply with Article 6 of the PCT for being directed to the desired result rather than to the combination necessary to achieve that result as described in the description.

Claims 70, 71, 73 do not comply with Article 6 of the PCT for being directed to the desired result rather than to the combination necessary to achieve that result as described in the description. Specifically, the portions of the claims, "the paste composition is non-newtonian, thixotropic and/or pseudoplastic", is directed to the desired result.

Claims 1, 2, 4, 70, 71, 73 lack conciseness and do not comply with Article 6 of the PCT and Rule 6.1(a) of the PCT. The claims should not be unduly multiplied so as to obscure the definition of the claimed invention. The number of claims shall be reasonable in consideration of the nature of the alleged invention claimed.

Claim 9 does not comply with Article 6 of the PCT. The claim shall be clear and concise. The inclusion of the expression "such as" causes ambiguity.

Claim 21 does not comply with Article 6 of the PCT. The claim shall be clear and concise. The claim does not explicitly define what the "non-dissolved particles" are. Also, it is unclear whether the particles must be less than 100 microns OR may be more than 100 microns but less than 200 microns OR may be more than 200 microns but less than 500 microns OR may be more than 500 microns but less than 1000 microns.

Claims 27-30 do not comply with Article 6 of the PCT. The claims shall be clear and concise. The expression "not significantly affected" does not define how affected the dissolution is nor does it define in what way it is affected.

Claim 72 does not comply with Article 6 of the PCT. The claim shall be clear and concise. Claims 64 and 65 define uses rather than compositions. Perhaps dependence upon claim 71 was intended.

Claim 73 does not comply with Article 6 of the PCT. The claim shall be clear and concise. The claim is redundant in view of claim 72.

The statement found on page 9, lines 4-11 of the description does not comply with Article 6 of the PCT. This is a general statement which implies that the extent of protection may be expanded in some vague and imprecise way.